ETEX Corporation Medical Device Special 510(k) Submission
OssiFuse Bone Substitute Material

510(k) SUMMARY AS REQUIRED UNDER 21 CFR 807.87(h)

K072355

SEP 26 2007

1. **Submitted By:** ETEX Corporation
38 Sidney Street, 3rd Floor
Cambridge, MA 02139

Contact Person: Pamela W. Adams, R.A.C.
Senior Vice President and Chief Operating Officer

Date Prepared: August 15, 2007

FDA Establishment Number: 1225112

2. **Proprietary Name:** OssiFuse Bone Substitute Material
Common Name: Bone Void Filler
Device Class: Class II
Product Code: MQV

3. **Legally Marketed Device for Substantial Equivalence Comparison:**
Product: CaP_3 Bone Substitute Material
Product Code: MQV
Manufacturer: ETEX Corporation
510(k) #: K033138

4. **Comparison to the Predicate Device:**
OssiFuse Bone Substitute Material is a synthetic bone substitute material that is similar to CaP_3 Bone Substitute Material. OssiFuse and CaP_3 have the same type and duration of patient contact, chemical composition, fundamental scientific technology and intended use. The handling characteristics are slightly different to enable delivery of the material through a needle. Once in the body, the material will perform in a similar manner due to the fact it is the same previously cleared material.

5. **Device Description:**
OssiFuse Bone Substitute Material is a synthetic, biocompatible bone graft substitute material. It is intended for use in bone void filler applications in the spine, pelvis, and extremities. At the time of use, the OssiFuse powder component is combined with the mixing liquid and is mixed to form a paste. Mixing is facilitated by a syringe to syringe mixing system. The resulting paste can be administered to the treatment site by manual application or injection, and can be shaped in situ or into a desired

form prior to implantation. After the paste is applied to the treatment site, it hardens at body temperature and converts to an apatitic calcium phosphate material. The end product, poorly crystalline hydroxyapatite (PCHA), is of low crystalline order and has a similar chemical identity and crystalline structure to that of the mineral content of natural bone. OssiFuse Bone Substitute Material is an osteoconductive material that is resorbed and replaced by natural bone over time.

6. Indications for Use

OssiFuse Bone Substitute Material is intended for use in filling bone voids or defects of the skeletal system (such as the extremities, spine and pelvis) that are not intrinsic to the stability of the bony structure. These defects may be surgically created osseous defects or osseous defects created from traumatic injury to the bone. OssiFuse Bone Substitute Material is a bone graft substitute that resorbs and is replaced with new bone during the healing process.

7. Substantial Equivalence

In summary, the OssiFuse Bone Substitute Material described in this submission is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Etex Corporation
% Ms. Pamela W. Adams, RAC
Senior Vice President & Chief Operating Officer
38 Sidney Street
Cambridge, MA 02139

SEP 26 2007

Re: K072355
Trade/Device Name: OssiFuse Bone Substitute Material
Regulation Number: 21 CFR 888.3045
Regulation Name: Resorbable calcium salt bone void filler device
Regulatory Class: II
Product Code: MQV
Dated: August 21, 2007
Received: August 27, 2007

Dear Ms. Adams:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

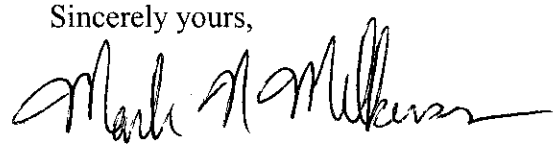
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at toll-free number (800) 638-2041 or (240) 276-3150 or the Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

ETEX Corporation Medical Device Special 510(k) Submission
OssiFuse Bone Substitute Material

INDICATIONS FOR USE STATEMENT

510(K) Number (if known)

Device Name OssiFuse Bone Substitute Material

Indications for use OssiFuse Bone Substitute Material is an implantable bone graft that is a synthetic calcium phosphate, poorly crystalline hydroxyapatite material intended for use in filling bone voids or defects of the skeletal system (such as the extremities, spine and pelvis) that are not intrinsic to the stability of the bony structure. These defects may be surgically created osseous defects or osseous defects created from traumatic injury to the bone. OssiFuse Bone Substitute Material is a bone graft substitute that resorbs and is replaced with new bone during the healing process.

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K072353

Prescription Use X OR Over-The Counter Use _____

(Per 21 CFR 801.109)